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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

O HARA, EILEEN B

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 09/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/746,375

Applicant(s)

PRESNELL ET AL.

Examiner

Eileen O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 24-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-20, 22 and 24-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 28-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22 and 24-32 ^{were} ~~are~~ subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-22 and 24-32 are pending in the instant application. Claims 21 and 28 have been amended, claim 23 has been canceled and claims 29-32 have been added as requested by Applicant in Paper Number 12, filed May 22, 2003.

Claims 1-20, 22 and 24-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 21 and 28-32 are currently under examination.

Priority

2. Applicants' amendment to the specification to recite the priority claimed in the declaration is acknowledged.

Objection to Specification

23. The objection to the specification is withdrawn in view of Applicants' amendment.

Claim Objections

4. Claims 28, 29 and 31 are objected to because of the following informalities:

4.1 On line 5 of both claims, the phrase "the labeled polynucleotide" is missing and should be inserted before the phrase "under conditions".

4.2 Claim 31 is objected to because the word "cause" on the second line is grammatically incorrect. It is suggested that "cause" be replaced with "caused by".

Appropriate correction is required.

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 21 and 28 remain rejected and new claims 29-32 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial utility or a well established utility, for reasons of record in the previous office action, Paper No. 9, at pages 3-6, and below.

Applicants traverse the rejection and assert a specific and utility and a well-established utility for the claimed methods in the specification. Applicants assert that it is well established “when a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown”, and cite *Raytheon C. v. Roper Corp.* Applicants contend on page 8 of the response that the Office has not established a prima facie showing of lack of utility, nor provided sound scientific reasoning to rebut the assertion of utility in the application, and that when a patent application claiming a nucleic acid asserts a specific, substantial and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion. Applicants assert that one of skill in the art upon reading the specification would appreciate that ZCYTO18 is a pro-inflammatory cytokine, and that the methods of using polynucleotides of the present invention are useful because it is asserted in the specification that such polynucleotides can be used as a marker for a specific human chromosomal locus or to detect inflammation or activated T-cells.

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Applicants assert on pages 9-11 of the response that the specification asserts the methods using polynucleotides of the present invention can be used to detect chromosomal abnormalities in a specific region of human chromosome 12q15, to which instant claims 21 and 32 are drawn. Applicants contend that because gross chromosomal aberrations at chromosome 12q15 are clearly associated with human disease, and it is well settled in the art how to use such polynucleotides as probes, this utility is substantial and credible, and it is well known in the art that markers for genetic diseases and chromosomal abnormalities are sought after, and the Office has presented no evidence to the contrary to refute that the polynucleotides of the present invention could be used as a specific chromosomal marker for 12q15.

Applicants' arguments have been fully considered but are not deemed persuasive. While it is credible that the polynucleotides of the instant invention can be used as a chromosomal marker for 12q15, this is not a substantial utility. On page 5-6 of the "Revised Interim Utility Guidelines", it is stated:

"Specific utility"— A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

Although the chromosomal location has been determined for this gene, any other nucleic acid derived from this chromosomal region may also be used in the same manner. The asserted use for this polynucleotide is to detect gross chromosomal abnormalities associated with loss of heterozygosity, translocation, rearrangements, large deletions and insertions, chromosome gain,

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DNA amplification and the like, which can be done with any polynucleotide from this chromosomal region. The polynucleotides have not been associated with any specific disease or disorder. Therefore, the asserted utility is not specific and substantial,

On pages 11-12 of the response, Applicants assert that the polynucleotides of the instant invention can be used to detect inflammation, to which claims 28 and 31 are drawn. Applicants assert that the specification discloses that the polynucleotides of the present invention are expressed in activated T-cells (particularly CD3+ T-Cells), and such T-cells are important mediators of inflammation as asserted in the specification, and the polypeptides are pro-inflammatory in animals.

Applicants' arguments have been fully considered but are not deemed persuasive. The specification on pages 14-15 disclose that ZCYTO18 is expressed in activated peripheral blood cells, which were selected for CD3, and that ZCYTO18 polynucleotides are expressed in T-cells, activated T- and B- cells, and lymphoid tissue. From this tissue or cell type distribution, the polynucleotides would also be expressed under non-inflammatory conditions.

Applicants assert on pages 12-13 that the polynucleotides of the present invention can be used to detect activated T-cells, to which claims 29 and 30 are drawn, and this is a specific utility. Applicants' arguments have been fully considered but are not deemed persuasive. The specification teaches that ZCYTO18 is expressed in activated T-cells as well as in T-cells. Additionally, activated T cells also express other molecules that could be used to detect them (for example CD2R, CD9, CD25, CD26, CD30, CD49a, CD69, CD96, CD97, CD134, for example), therefore this is not considered to be a specific and substantial utility.

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For these reasons and those of record in the previous Office Actions, the rejection under 35 USC § 101 is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 21 and 28 also remain rejected, and new claims 29-32 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Effective Priority Date

35 U.S.C. § 119(e) states that:

An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, by an inventor or inventors named in the provisional application, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application.

7. Applicant is advised that the instant application can only receive benefit under 35 U.S.C. § 119(e) from an earlier application which meets the requirements of 35 U.S.C. § 112, first paragraph, with respect to the now claimed invention. Because the instant application does not meet the requirements of 35 U.S.C. § 112, first paragraph, for those reasons given above, the prior applications do not meet those requirements and, therefore, are unavailable under 35 U.S.C.

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§ 119(e). The effective priority date of the instant application is considered to be the filing date of this application, Dec. 22, 2000, because the claimed invention is not supported by either a specific and substantial utility or a well established utility.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 28 is rejected under 35 U.S.C. 102(a) as being anticipated by Parham et al., WO 00/73457 A1, Dec. 7, 2000, for reasons of record in the previous office action, Paper No. 9, at pages 6-7.

The claim was mistakenly rejected under 35 U.S.C. 102(b), but is now rejected under 35 U.S.C. 102(a). Applicants submit that the provisional applications filed Dec. 23, 1999 and Dec. 1, 2000 are evidence that the Parham et al. reference is not available as prior art under 35 U.S.C. 102(a), since the instant application claims priority to them, and in particular, Applicants present that the filed patent applications show constructive reduction to practice of the methods of using ZCYTO18 polynucleotides to detect inflammation.

Applicants' arguments have been fully considered but are not deemed persuasive. Since the methods of the instant application do not have a specific and substantial utility as described above, the effective filing date is the actual filing date of the application, Dec. 22, 2000.

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Advisory Information

9. It is noted that claim 31 as written encompasses a method of detecting inflammation, wherein the inflammation is caused by all of the diseases listed being present at the same time. If Applicants intend that the inflammation is caused by one of these diseases in the alternative, the word "and" on the third line should be replaced with "or".

It is believed that all pertinent arguments have been answered.

Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

A handwritten signature in black ink that reads "Eileen B. O'Hara". The signature is written in a cursive, flowing style.